

EPO - DG 1

05. 02. 2005

35

R2647-PCT

(54)

CLAIMS

1. An apparatus for the continuous wet granulation of a powder material, comprising:
- 5 - a barrel having a granulation chamber provided between a first part (B) and a second part (B') of said barrel, the first part (B) being provided with at least one first inlet (1) connected with said granulation chamber for receiving said powder material and for supplying it to said granulation chamber and with at least one second inlet (2) connected
- 10 with said granulation chamber for receiving a granulating liquid and for supplying it to said granulation chamber, said granulation chamber having an aperture (9) for discharge of granules from said barrel, and
- at least one continuously operated transporting means (S) provided in said granulation chamber for continuously advancing said powder
- 15 material toward the end of said granulation chamber while granulating said powder material with the aid of said granulating liquid, each said transporting means (S) comprising at least a first transport zone (4) at its rear end, an agglomeration zone (5) downstream from the first transport zone (4) for effecting particle size enlargement of said powder
- 20 material and contributing to advancing said powder material through said transporting means (S), and a second transport zone (8) at its front end, said at least one first inlet (1) and said at least one second inlet (2) of the barrel being positioned above the at least one first transport zone (4) of each said at least one transporting means (S),
- 25 wherein said aperture (9) has a shape tightly fitting the terminal portion of said at least one transporting means (S) for directly discharging said granules from the granulation chamber without developing a pressure gradient at the exit of the granulation chamber.
- 30 2. An apparatus according to claim 1, characterised in that each said at least one transporting means (S) further comprises one or more additional transport zones (6, 8) and one or more additional agglomeration zones (7),

each agglomeration zone (5, 7) being positioned between two transport zones (4, 6, 8).

3. An apparatus for the continuous wet granulation of a powder material, consisting essentially of:

- a barrel having a granulation chamber provided between a first part (B) and a second part (B') of said barrel, the first part (B) being provided with at least one first inlet (1) connected with said granulation chamber for receiving said powder material and for supplying it to said granulation chamber and with at least one second inlet (2) connected with said granulation chamber for receiving a granulating liquid and for supplying it to said granulation chamber, said granulation chamber having an aperture (9) for discharge of granules from said barrel, and
- at least one continuously operated transporting means (S) provided in said granulation chamber for advancing said powder material toward the end of said granulation chamber while granulating said powder material with the aid of said granulating liquid, each said transporting means (S) comprising at least a first transport zone (4) at its rear end and optionally one or more additional transport zones (6), an agglomeration zone (5) downstream from the first transport zone (4) and optionally one or more additional agglomeration zones (7), and a second transport zone (8) at its front end, each agglomeration zone (5, 7) being positioned between two transport zones (4, 6, 8), said at least one first inlet (1) and said at least one second inlet (2) of the barrel being positioned above the at least one first transport zone (4) of each said at least one transporting means (S),

wherein said aperture (9) has a shape tightly fitting the terminal portion of said at least one transporting means (S) for directly discharging said granules from the granulation chamber without developing a pressure gradient at the exit of the granulation chamber.

4. An apparatus according to claim 3, characterised in that said transporting means (S) is a rotating transporting means.

5. An apparatus according to claim 3 or claim 4, characterised in that said transporting means (S) is a single screw.
- 5 6. An apparatus according to claim 3 or claim 4, characterised in that said transporting means (S) is a twin screw.
7. An apparatus according to claim 5 or claim 6, characterised in that the length to diameter ratio of each screw is within a range from about 15 to
10 about 60.
8. An apparatus according to any of claims 3 to 7, characterised in that the cumulative lengths of the agglomeration zones (5, 7) represent from about 8% to about 30% of the length of the transporting means (S).
15
9. An apparatus according to any of claims 3 to 8, characterised in that the cumulative lengths of the agglomeration zones (5, 7) represent from about 10% to about 25% of the length of the transporting means (S).
- 20 10. An apparatus according to any of claims 3 to 9, characterised in that the respective dimensions of the first inlet (1) for receiving the powder material and of the second inlet (2) for receiving the granulation liquid are such that the weight ratio of the granulating liquid to the powder material is not above 16:100.
25
11. An apparatus according to any of claims 3 to 10, characterised in that the respective dimensions of the first inlet (1) for receiving the powder material and of the second inlet (2) for receiving the granulation liquid are such that the weight ratio of the granulating liquid to the powder material is not
30 above 12:100.
12. An apparatus according to any of claims 3 to 11, characterised in that the respective dimensions of the first inlet (1) for receiving the powder material

and of the second inlet (2) for receiving the granulation liquid are such that the weight ratio of the granulating liquid to the powder material is not above 8:100.

- 5 13. An apparatus according to any of claims 3 to 12, characterised in that the respective dimensions of the first inlet (1) for receiving the powder material and of the second inlet (2) for receiving the granulation liquid are such that the weight ratio of the granulating liquid to the powder material is not below 2:100.
- 10 14. An apparatus according to any of claims 3 to 13, characterised in that the respective dimensions of the first inlet (1) for receiving the powder material and of the second inlet (2) for receiving the granulation liquid are such that the weight ratio of the granulating liquid to the powder material is not below
- 15 4:100.
15. A process for the continuous wet granulation of a powder material, comprising continuously operating an apparatus according to any of claims 3 to 14.
- 20 16. A process for the continuous wet granulation of a powder material, comprising the steps of :
- (a) feeding a powder material to a first transport zone (4) of at least one continuously operated transporting means,
- 25 (b) feeding a granulating liquid to said first transport zone (4) of said at least one continuously operated transporting means,
- (c) continuously advancing said powder material and said granulating liquid from said first transport zone (4) to an agglomeration zone (5) of said at least one continuously operated transporting means
- 30 downstream of said first transport zone (4) for agglomerating said wet powder material,
- (d) transporting said agglomerated material from said agglomeration zone (5) to a second transport zone (8) of said at least one continuously

operated transporting means downstream of said agglomeration zone (5) for producing granules, and
(e) directly discharging said granules from said second transport zone (8) of said at least one continuously operated transporting means without
5 submitting said granules to any pressure gradient.

17. A continuous wet granulation process according to claim 16, further comprising the step of continuously advancing said agglomerated material from said agglomeration zone (5) to said second transport zone (8) of said
10 at least one continuously operated transporting means through one or more combinations of an additional intermediate transport zone (6) followed by an additional intermediate agglomeration zone (7).

18. A continuous wet granulation process according to claim 16 or claim 17,
15 characterised in that said at least one continuously operated transporting means is a rotating transporting means.

19. A continuous wet granulation process according to any of claims 16 to 18, characterised in that said at least one continuously operated transporting
20 means is a single screw.

20. A continuous wet granulation process according to any of claims 16 to 18, characterised in that said at least one continuously operated transporting
25 means is a twin screw.

21. A continuous wet granulation process according to any of claims 16 to 20, characterised in that the residence time of said powder material in said at least one continuously operated transporting means is in the range of about 5 seconds to about 180 seconds.
30

22. A continuous wet granulation process according to any of claims 16 to 21, characterised in that the residence time of said powder material in said at

least one continuously operated transporting means is in the range of about 20 seconds to about 60 seconds.

- 5 23. A continuous wet granulation process according to any of claims 16 to 22, characterised in that said powder material contains a biologically-active ingredient.
- 10 24. A continuous wet granulation process according to claim 23, characterised in that the content of said biologically-active ingredient in powder material is within a range from 0.1% by weight to 99% by weight.
- 15 25. A continuous wet granulation process according to claim 23 or claim 24, characterised in that said biologically-active ingredient is a poorly soluble drug belonging to Class II or Class IV of the Biopharmaceutical Classification System.
- 20 26. A continuous wet granulation process according to any of claims 16 to 22, characterised in that said powder material is selected from foodstuffs, catalysts, chemicals, fertilisers, detergents and mineral ores.
- 25 27. A continuous wet granulation process according to any of claims 16 to 26, characterised in that the amount of the said granulating liquid is from about 2% to about 16% by weight of the powder material.
28. A continuous wet granulation process according to any of claims 16 to 27, characterised in that the amount of the said granulating liquid is from about 4% to about 12% by weight of the powder material.
- 30 29. A continuous wet granulation process according to any of claims 16 to 28, being carried out at a temperature within a range from about 10°C to about 50°C.

30. A continuous wet granulation process according to any of claims 16 to 29, characterised in further comprising a granule drying step (f) subsequent to discharging step (e).
- 5 31. A continuous wet granulation process according to any of claims 16 to 30, characterised in further comprising a granule dry milling step subsequent to discharging step (e).
- 10 32. A continuous wet granulation process according to any of claims 23 to 25, characterised in that said powder material further contains one or more physiologically acceptable excipients.
- 15 33. A granule population obtained by operating an apparatus according to any of claims 3 to 14 or by performing a process according to any of claims 15 to 32.
34. A granule population according to claim 33, having an average size within a range from about 250 μm to about 1,000 μm .
- 20 35. A granule population according to claim 33 or claim 34, having an average size within a range from about 250 μm to about 700 μm .
36. A solid shaped article obtained from a granule population according to any of claims 33 to 35.
- 25 37. A solid shaped article according to claim 36, in the form of a tablet, a composite article or a capsule.
- 30 38. A solid shaped article according to claim 37, being a tablet obtained by compressing the said granule population.